UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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HOU LIU, et al.,

Plaintiffs,

-against- 17-cv-7371 (LAK)

INTERCEPT PHARMACEUTICALS, INC., et al.,

Defendants.

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MEMORANDUM OPINION

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LEWIS A. KAPLAN, *District Judge.*

On March 26, 2020, the Court granted defendants' motion to dismiss the amended

complaint and directed the Clerk to close the case.[1] The matter is now before the Court on plaintiffs' motion to amend the judgment under Federal Rule of Civil Procedure 59(e) or alternatively set it aside pursuant to Rule 60(b), and for leave to file their Proposed Second Amended Complaint ("PSAC"). They claim that such relief is necessary to correct the Court's "clear error" of closing the case without granting them leave to amend, as requested in one sentence at the conclusion of their opposition to defendants' motion to dismiss. Defendants contend that plaintiffs have failed to satisfy their burdens under Rules 59(e) and 60(b) and, in any event, that the Court should deny leave to amend because the proposed amendments would be futile.

Discussion

I. The Court's Prior Opinion

The Court assumes familiarly with its prior opinion dismissing the case. For purposes of this motion, it suffices to say only the following:

> "This putative securities class action is born out of thirty reports of death or serious injury (the Serious Adverse Events, or 'SAEs') that occurred over a one year period in twenty-seven – out of approximately 3,000 – users of Ocaliva, defendant Intercept Pharmaceuticals's drug to treat patients with the rare liver disease primary biliary cholangitis ('PBC')."[2]
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> "These thirty SAEs comprised of nineteen deaths and eleven cases of serious liver injury."[3]

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1 *Liu v. Intercept Pharm., Inc.*, 17-cv-7371 (S.D.N.Y.), DI 91, 92.

2 *Liu v. Intercept Pharm., Inc.*, No. 17-cv-7371 (LAK), 2020 WL 1489831, at *1 (S.D.N.Y Mar. 26, 2020).

3 *Id.* at *3.

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"Recognizing that the livers of patients with late-stage PBC are more compromised, and therefore more vulnerable to the drug's toxicity, the FDA [had] recommended that late-stage patients take lower doses of Ocaliva than patients with early stages of the disease."[4]

* * *

"Of the twenty-seven patients [known to have suffered a serious adverse event], twelve of the thirteen known late-stage PBC patients received an incorrect dose."[5]

* * *

"Pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), Intercept must submit reports of any adverse events to the FDA. . . . Intercept complied with this regulation and its pharmacovigilance department submitted the [thirty] reports to the FDA."[6]

* * *

"On September 12, 2017, Intercept issued a 'Dear Healthcare Provider Letter' (the 'HCP Letter') warning providers against prescribing late-stage PBC patients with a dose higher than recommended. The letter explained that Intercept had received reports of '[l]iver injury, liver decompensation, liver failure, and death' after patients had taken incorrect doses.' It stated also that some early-stage PBC patients reported serious liver adverse events. Intercept urged healthcare providers to ensure that patients with late-stage PBC received the correct drug dose and to monitor all Ocaliva patients for liver-related adverse reactions.

"Following publication, Intercept's common stock fell from a close of $113.48 on September 11, 2017 to a close of $90.75 on September 13, 2017."[7]

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4 *Id.* at *1.

5 *Id.* at *3.

6 *Id.*

7 *Id.*

> "On September 21, 2017, the FDA issued a drug safety communication (the "Communication") and a corresponding safety alert summarizing the Communication, on the SAEs reported by Ocaliva users. The data included in the Communication came directly from the adverse events reported to the FDA by Intercept. The FDA warned that Ocaliva was 'being incorrectly dosed in some patients with [late-stage PBC], resulting in an increased risk of serious liver injury and death.' It cautioned providers against prescribing higher than the suggested dose and recommended frequent monitoring of Ocaliva patients.
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> "Intercept's common stock price fell from $98.12 per share on September 20, 2017 to close at $61.59 per share on September 22."[8]
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> "Ocaliva remains on the market."[9]

Plaintiffs argued that in light of the twenty-seven Ocaliva users who took an incorrect dose of Ocaliva and/or suffered SAEs, certain of defendants' prior statements were materially false or misleading in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. The statements were categorized broadly as those:

> (1) concerning Ocaliva's safety and tolerance, (2) related to patients' compliance with the FDA-recommended dosing regimen, and (3) made following the HCP Letter related to the severity and scope of the SAEs. These statements allegedly were made at conferences, on earning calls, or included in public company presentations, analyst reports, and SEC filings."[10]

The Court concluded that plaintiffs had failed to allege sufficiently a material misstatement or omission. It dismissed the amended complaint on the additional ground that it did not sufficiently allege *scienter* as required by Rule 9(b) and the PSLRA.

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8 *Id.*

9 *Id.* at *4.

10 *Id.*

II. Legal Standards

"A party seeking to file an amended complaint post-judgment must first have the judgment vacated or set aside pursuant to [Federal Rules of Civil Procedure] 59(e) or 60(b)."[11] Both rules hold the moving party to "stringent standards."[12]

Relief under Rule 59(e) should be granted only in limited circumstances, such as where the court overlooked controlling law or factual matters put before it. "Alternatively, a court may grant a Rule 59(e) motion based on an intervening change in law, newly discovered evidence, or 'to correct a clear error or prevent manifest injustice.'"[13] Rule 60(b) is "a mechanism for extraordinary judicial relief invoked only if the moving party demonstrates exceptional circumstances."[14] The movant must present "highly convincing" evidence and "show good cause for the failure to act sooner."[15]

Plaintiffs have not pointed to any facts or controlling decisions that the Court overlooked in dismissing the amended complaint. Nor do plaintiffs offer any newly discovered evidence or show that relief is necessary to prevent manifest injustice. Instead, plaintiffs' motion

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11 *Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008).

12 *Axar Master Fund, Ltd. v. Bedford*, 806 F. App'x. 35, 39 (2d Cir. 2020).

13 *Ong v. Chipotle Mexican Grill, Inc.*, 329 F.R.D. 43, 50 (S.D.N.Y. 2018), *aff'd sub nom. Metzler Inv. Gmbh v. Chipotle Mexican Grill, Inc,* No. 18-3807-cv, 2020 WL 4644799 (2d Cir. Aug. 12, 2020) (quoting *In re Initial Pub. Offering Sec. Litig.*, 399 F. Supp. 2d 261, 262 (S.D.N.Y. 2005)).

14 *Ruotolo*, 514 F.3d at 191 (internal quotation marks and citation omitted).

15 *Axar Master Fund,* 806 F. App'x. at 40 (citation omitted).

hinges entirely on its contention that the Court committed "clear error" by closing the case without granting plaintiffs leave to amend their complaint.

Doing so was well within the Court's discretion. Indeed, it is proper for a court to "deny leave to amend implicitly by not addressing the request" where, as here, "leave is requested informally in a brief filed in opposition to a motion to dismiss."[16] Hence, the Court did not "clear[ly] err[]" by instructing the Clerk to enter a final judgment without permitting plaintiffs to amend their complaint.

However, while "the standards we have developed for evaluating postjudgment motions generally place significant emphasis on the 'value of finality and repose,'" those considerations, in light of Rule 15's liberal amendment policy, "do not always foreclose the possibility of amendment."[17] Therefore, "it might be appropriate in a proper case to take into account the nature of the proposed amendment in deciding whether to vacate the previously entered judgment."[18] This is true particularly where, as here, a plaintiff has not had an opportunity to amend its complaint following the action's dismissal.[19]

Mindful of this, the Court will exercise its discretion to consider whether plaintiffs have shown that the Court's judgement should be set aside or amended in light of the PSAC. This

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16 *Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 220 (2d Cir. 2006), *abrogated on other grounds by FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *see, e.g., Corsini v. Nast,* 613 F. App'x 1, 4 (2d Cir. 2015).

17 *Williams v. Citigroup Inc.*, 659 F.3d 208, 213 (2d Cir. 2011) (quoting *In re Frigitemp Corp.*, 781 F.2d 324, 327 (2d Cir. 1986)).

18 *Id.*

19 *See Metzler Inv. Gmbh.*, 2020 WL 4644799, at *10-11 (2d Cir. 2020).

analysis turns on whether the proposed amendments would be futile.[20] "An amendment to a pleading is futile if the proposed claim could not withstand a motion to dismiss pursuant to [Federal Rule of Civil Procedure] 12(b)(6)."[21] Hence, the judgment entered previously will be set aside or amended only if the PSAC contains additional allegations that cure the deficiencies that the Court identified in the amended complaint.

III. Scienter

To plead *scienter* sufficiently, the complaint must state with particularity facts demonstrating either that (1) "defendants had both motive and opportunity to commit fraud," or (2) "constitute strong circumstantial evidence of conscious misbehavior or recklessness."[22] "When the defendant is a corporate entity . . . the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite *scienter*."[23]

A. Motive and Opportunity

The PSAC does not include new allegations of a motive and opportunity to commit fraud. Instead, it simply recycles those that the Court had rejected already. Those allegations do

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20 *See Kim v. Kimm*, 884 F.3d 98, 106 (2d Cir. 2018).

21 *Lucente v. Int'l Bus. Machs. Corp.*, 310 F.3d 243, 258 (2d Cir. 2002).

22 *Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001).

23 *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008).

not raise a strong inference of *scienter* for the reasons explained in the Court's prior opinion.[24]

B. Recklessness

Where, as here, a complaint does not allege sufficiently allegations of motive and opportunity, allegations of recklessness "must be correspondingly greater."[25] "For a defendant's conduct to qualify as reckless, it is not enough to allege a mere 'heightened form of negligence;' the defendant's conduct must have been 'highly unreasonable'—that is to say, 'an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'"[26] Examples include a defendant's "knowledge of facts or access to information contradicting their public statements . . . [when the defendant] knew or, more importantly, or should have known that they were misrepresenting material facts" or if a defendant "failed to review or check information that [it] had a duty to monitor, or ignored obvious signs of fraud."[27]

Allegations of recklessness are judged against the PSLRA's exacting requirement that the complaint state with particularity facts that give rise a "strong inference" of *scienter*. Under this standard, the Court "must engage in a comparative evaluation; it must consider, not only inferences

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24 *Intercept*, 2020 WL 1489831, at *14.

25 *Kalnit*, 264 F.3d at 142.

26 *City of Westland and Fire Ret. Sys. v. MetLife, Inc.*, No 12-cv-0256 (LAK), 2016 WL 6652731, at *12 (S.D.N.Y Nov. 10, 2016) (quoting *S. Cherry St. LLC v. Hennessee Grp. LLC.*, 573 F.3d 98, 109 (2d Cir. 2009)).

27 *Novak v. Kasaks*, 216 F. 3d 300, 308 (2d Cir. 2000).

urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged."[28]

In relevant part, the Court previously held that plaintiffs had not alleged sufficiently that (1) the Individual Defendants (a) had knowledge of or access to information contradicting their public statements at the time those statements were made or, in the alterative, (b) were reckless in not reviewing the relevant information, (2) *scienter* could be imputed to the company, and (3) defendants' lawful challenge to plaintiffs' request for documents from the European Medical Agency raised an inference of *scienter*.[29] Plaintiffs argue that they have cured these defects.

1. Individual Defendants

a. Knowledge of or Access to Information

In opposing defendants' motion to dismiss, plaintiffs argued that the Individual Defendants "were aware of the reported SAEs because [they] made statements about Ocaliva's safety and tolerability and therefore 'would necessarily [would] have had to review the safety information collected by the Company.'"[30] Similarly, they contended that the Individual Defendants' statements related to dosing compliance "'evidenc[ed] their familiarity with [Intercept's patient services hub and internal database] Interconnect and the Ocaliva dosing data' from which *scienter* [could] be inferred."[31] In rejecting this argument the Court noted, among other defects, that

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28 *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

29 *Intercept*, 2020 WL 1489831, at *14-19.

30 *Id.* at *15.

31 *Id.*

plaintiffs had not alleged particularized facts "from which the Court could infer that the Individual Defendants knew, *at the time the statements were made*, that patients had been misdosed or of the existence, scope, or severity of the adverse events that had been reported."[32] Instead, plaintiffs' argument amounted to the insufficient conclusory allegation that the Individual Defendants "would necessarily" have had to know about the misdosing and reported SAEs before making certain statements.[33]

Plaintiffs contend that they have amended their complaint to "clarify" the allegations as to *scienter*. Yet, plaintiffs argue again that certain statements demonstrate that the Individual Defendants must have been familiar with the dosing data and reports of SAEs, thereby demonstrating that the Individual Defendants had knowledge of information that contradicted their public statements.

"A plaintiff cannot base securities fraud claims on speculation and conclusory allegations."[34] In light of this foundational principle, allegations that defendants "must have reviewed" or "been aware of" certain types of information are not sufficient to plead *scienter*.[35] Once again, this is precisely what plaintiffs have alleged.

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32 *Id.* (emphasis in original).

33 *Id.*

34 *Kalnit*, 264 F.3d at 142.

35 *See, e.g.*, *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d. 553, 572 (S.D.N.Y. 2014) ("An allegation that a defendant merely ought to have known is not sufficient to allege recklessness"); *Local No. 38 Intern. Broth. of Elec. Workers Pension Fund v. American Exp. Co.*, 724 F. Supp. 2d 447, 462 (S.D.N.Y. 2010) (finding "information was the sort of [data]" that "would have been reviewed by the Individual Defendants" was "too speculative to give rise to a strong inference of *scienter*").

As to statements on dosing, plaintiffs argue that the PSAC contains "additional detailed statements" – including some that Court held already did not raise a strong inference of *scienter*[36] – that demonstrate that "Defendants would have had to have reviewed reports or data regarding which patients were taking which doses of Ocaliva, which would have indicated that patients with late-stage PBC were taking the wrong dose."[37] These include statements such as: "right now, what we can see through Interconnect is around 95% of the patients start on the 5 milligram dose"; "the vast majority of patients have not yet titrated up from 5 milligrams to 10 milligrams"; and "we do see patients with complicated cirrhosis that are being treated with Ocaliva, but we're not really seeing major differences as far as the treatment approach to those patients."[38]

The Court once again rejects plaintiffs' argument that the statements on patients' doses themselves raise a strong inference of *scienter*. Those statements concern how many users were prescribed a particular dosage. The number of patients who were prescribed the incorrect drug dose, given the stage of their disease, is a metric entirely different from the number of patients who were prescribed a drug dose of 5 or 10 milligrams. For example, knowledge that 5 percent of users took a 10 milligram dose says nothing about how many of those users were appropriately taking a 10 milligram dose. This distinction is key, as the alleged fraud is that the statements on patient dosing and compliance were false or misleading because certain patients had been misdosed. The statements thus do not demonstrate that the Individual Defendants were aware, at the time they were made, that some Ocaliva users – between two to twelve individuals, out of 3,000 users, depending

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36 *See Intercept*, 2020 WL 1489831, at *16.

37 DI 96 at 25.

38 PSAC [DI 98-1] ¶ 179.

on when the statement was made – had been prescribed an incorrect dose of Ocaliva. Rather, the statements establish only that the speakers "were aware of [the amount of Ocaliva taken by patients], not that they knew that their disclosures were false or misleading."[39]

Plaintiffs' argument as to the safety and tolerance statements is somewhat more persuasive, but ultimately fares no better. They contend that the Individual Defendants, in order to make these statements, "must have reviewed information regarding the adverse safety events being experienced by patients taking Ocaliva."[40] Among the statements cited in support of this allegation are: "side effects like pruritus [an itching of the skin] are manageable with dose titration"; "I mean, we do obviously have reports that are reported in, but generally, we're not hearing a lot more issues out there," in reference to a question on "safety pushback"; "we haven't – no red flags right now . . . [T]hus far, nothing out of the ordinary," in response to a question on whether Intercept was seeing an increased number of reports of side effects; and that, according to a survey of physicians, the "[t]op motivation" to prescribe Ocaliva was based "on strong beliefs on efficacy and no serious side effects."[41]

As to the statements on pruritus, plaintiffs contend that if information reviewed by the Individual Defendants prior to speaking "contained data about pruritus, it certainly must have contained information regarding the most serious safety events, death and liver injury."[42] This is

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39 *Pennsylvania Pub. Sch. Emps.' Ret. Sys. v. Bank of America Corp.*, 874 F. Supp. 2d 341, 360 (S.D.N.Y. 2012).

40 DI 96 at 26.

41 PSAC ¶¶ 113, 119, 127, 184.

42 DI 96 at 26.

nothing more than speculation, even accepting plaintiffs' position that the Individual Defendants must have reviewed information on the more serious side effects in order to make any statement on pruritus.

First, plaintiffs ask the Court to assume, without any particularized allegations, that any report that contained information on pruritus contained also information on the serious adverse events of serious liver injury and death, the subjects of the alleged fraud. This type of conjecture cannot survive the PSLRA and Rule 9(b)'s heightened pleading standard.

Second, plaintiffs do not identify any reports that allegedly contained information on pruritus. To allege adequately that defendants knew or had access to facts that contradicted their public statements, plaintiffs must "specifically identify the reports or statements containing this information."[43] The PSAC specifically identifies the adverse event reports. It alleges that those reports contained information on patient deaths, instances of serious liver injury and, in some instances, the patients' stage of PBC and the dose of Ocaliva prescribed. [44] The PSAC does not, however, allege that the adverse event reports contained information on less serious side effects, such as pruritus. The Court therefore cannot infer knowledge of the reported serious adverse events from the statements made on pruritus.

Nor may *scienter* be inferred from the other statements on tolerance and safety. The cases plaintiffs cite are informative. In *In re General Electric Company Security Litigation*, an individual defendant made statements about the financial health of the corporate defendant's loan portfolio, including "detailed accounts" regrading its delinquency rates, the location of its borrowers,

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43 *Novak*, 216 F.3d at 309.

44 PSAC ¶¶ 88-89.

and the average size of its debts, loans, and loan loss reserves.[45] The district court concluded that "[i]n order to speak so knowledgeably regarding the state of [the corporation]'s finances, [the speaker] must have educated himself regarding [the corporation's] financial health," which was the subject of the alleged fraud.[46] The court therefore held that an inference of *scienter* would have been permissible from the defendant's statements.[47]

Similarly, in *Hawaii Structural Ironworkers Pension Trust Fund v. AMC Entertainment Holdings, Inc.*, plaintiffs alleged that defendants failed to disclose that Carmike Cinema had underinvested significantly in its theaters.[48] An individual defendant had made statements on AMC's ability to renovate Carmike theaters, including that the determination to renovate was made "one at a time, theater by theater," and that "we have identified that there are an easy 50 to 100 Carmike theaters that are capable of supporting an AMC-style renovation."[49] "To underscore the thoroughness of the due diligence performed, [the individual defendant] pointed to the fact that AMC had 'spent eight months with the Justice Department of the United States.'"[50] The court concluded that in order to speak "so knowledgeably" on the state of Carmike's theaters, the defendant "must have educated himself" on the condition those theaters, "presumably by reviewing

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45 857 F. Supp. 2d 367, 395 (S.D.N.Y. 2012).

46 *Id.* at 395-96.

47 *Id.* at 396.

48 422 F. Supp. 3d 821, 836 (S.D.N.Y. 2019).

49 *Id.* at 850.

50 *Id.*

data given to him by Carmike and by performing his own due diligence."[51] Accordingly, the detailed statements "supported[ed] the inference that defendant was aware of Carmike's underinvestment in its theaters or had access to this information."[52] The court noted that other public statements were "much more general," and therefore could not support an inference that defendants knew or recklessly disregard certain information that was the subject of other allegations of fraud.[53]

In contrast, the statements identified by plaintiffs here, other than those that relate to pruritus, are not as detailed or specific. Instead, the statements such as those describing patient experience as "largely positive," expressing the opinion that, according a survey of physicians, Ocaliva's tolerability profile "is seen overall as good and manageable", and commenting that reports on side effects were "nothing out of the ordinary" were far more general.[54] It is of course plausible that the Individual Defendants had reviewed information on Ocaliva's tolerability before making those statements. It is plausible also that this information, depending on when the statement was made, would have included the fact that between one and thirty adverse events had been reported. But to allege securities fraud sufficiently, plaintiffs' allegations must be not only plausible, they must be pled with particularity. For the same reasons as explained above, the argument that the Individual Defendants "must have reviewed" information on adverse events, and therefore knew that

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51 *Id.*

52 *Id.*

53 *Id.*

54 PSAC ¶¶ 111, 113, 119.

their statements were false or misleading, fails adequately to allege *scienter* under the PSLRA and Rule 9(b).

Plaintiffs argue also that, by virtue of their positions within the company, the Individual Defendants had access to (1) Intercept's internal database, Interconnect, from which they "would have been able to pull from this system reports showing patients' stage of PBC and prescription dose, which would have indicated whether patients were complying with the dosing regimen," and (2) the adverse event reports received by the company's pharmacovigilance department, as well as the company's "internal analysis of [the SAE's] significance to the safety profile for Ocaliva."[55] But such allegations do not suffice. A defendant's senior position within a company does not support an inference that he or she had access to particular information or, more importantly, that such a defendant accessed it.[56] Nor, contrary to plaintiffs' argument, does the fact that the reported adverse events were available on the FDA's public database. [57] Moreover, even if the Court were to accept these allegations, they would fail to sufficiently plead *scienter*.

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55 *Id.* ¶¶ 177, 186.

56 *See In re Sanofi Sec. Lit.*, 155 F. Supp. 3d 386, 407 (S.D.N.Y 2016) (collecting cases).

57 In an effort to argue that the safety and tolerability statements were not actionable, defendants represented previously that the SAEs were disclosed publicly on the FDA's database, FAERS. DI 62 at 32. The Court rejected this argument, explaining that this "truth on the market" defense is "rarely an appropriate basis for dismissing a [Section] 10(b) complaint.'" *Intercept*, 2020 WL 1489831, at *6 n. 70 (quoting *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000)).

In light of defendants' representation, plaintiffs now contend that "if the SAE reports were available to the public, then they were certainly available to Defendants," and thus "Defendants' *scienter* is conclusively alleged." DI 96 at 26. Rather than "conclusively" demonstrate *scienter*, the public availability of the SAE reports undermines an inference of *scienter*. *See, e.g.*, *In re BHP Billiton Ltd Sec. Litig.*, 276 F. Supp. 3d 65, 92 (S.D.N.Y. 2017).

Allegations of access generally to reports, an internal analysis, or to a database are not particularized allegations sufficient to meet the PSLRA and Rule 9(b)'s exacting pleading standard.

For the foregoing reasons, the PSAC does not plead facts giving rise to a strong inference of *scienter* based on the Individual Defendants' alleged knowledge or access to contradictory information.[58]

b. Failure to Review Relevant Information

Plaintiffs argue that if the Individual Defendants did not review the adverse event reports or the dosing data prior to making the alleged misrepresentations, then this failure to do so raises a strong inference of *scienter*. In its prior opinion, the Court concluded that even if the

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58 This conclusion applies also to certain statements made following the HCP Letter, statements in which the Individual Defendants discussed the SAEs reported in Ocaliva users with late-stage PBC without mention of the SAEs suffered by five early-stage PBC patients. Plaintiffs argue that this omission was materially false or misleading.

The Court held previously that the amended complaint "allege[d] sufficiently that when the Individual Defendants made statements about the HCP Letter, they had knowledge of the adverse event reports. Indeed, the Individual Defendants were speaking directly about those reports." *Id.* at *16. However, the Court held that *scienter* was not plead adequately because the speakers' knowledge of adverse events in early-stage PBC patients did not "contradict" statements about the HCP letter, which, "squarely focused" on the SAEs reported in late-state PBC patients. *Id.* at *12, *16. As the Court noted previously, the letter includes only one sentence on early-stage PBC patients. *Id.* at *12.

Plaintiffs do not address directly how they have cured their *scienter* allegations as to the statements made by the Individual Defendants about the HCP Letter. The Court assumes that plaintiffs intended to do so by amending the PSAC as to why statements about the letter were allegedly false or misleading, particularly the inclusion of Pruzanski's statement from September 25, 2017. On that date, Pruzanski stated that "I want to clarify that [these early-stage PBC] cases were covered in our Dear Healthcare Provider Letter." PSAC ¶ 146. However, this allegation does not alter the Court's previous conclusion, which considered already that the letter included a reference to the SAEs in early-stage patients. Hence, the PSAC does not plead sufficiently that, when discussing the HCP Letter and speaking only about the data on the SAEs in late-stage patients, that the speakers intended to "deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976).

Individual Defendants had not reviewed the relevant data, at most the allegations amounted to an inference that they were negligent not to do so.[59] But, as explained previously, recklessness requires a "state of mind approximating actual intent, and not merely a heightened form of negligence."[60]

Plaintiffs argue that they now have included several facts sufficient to demonstrate that defendants acted with the requisite culpability. The PSAC alleges that the market was watching closely Ocaliva's commercial launch and that, as some analysts observed, any safety issues would jeopardize Ocaliva's chances of receiving FDA approval for the treatment of liver disorders other than PBC.[61] It alleges also that entering these new markets would have presented Intercept with a larger commercial opportunity.[62] In light of the new allegations, plaintiffs argue that defendants "would have been especially attuned to safety issues," and were "motivated to ignore or conceal any safety issues that may arise in PBC patients" so as not to risk Ocaliva's approval for other uses, and to "prevent any negative market or regulatory response."[63]

Plaintiffs argument as to a possible negative regulatory response rely on the implausible notion that the Individual Defendants' alleged failure to review reports of adverse events and misdosing would insulate Intercept from the risk that the FDA would not approve Ocaliva for the treatment of other liver conditions. As alleged elsewhere in the PSAC, the FDA was aware of

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59 *Intercept*, 2020 WL 1489831, at *16.

60 *Id.* (quoting *Novak*, 216 F.3d at 312).

61 PSAC ¶¶ 85, 196.

62 *Id.* ¶ 85.

63 *Id.* ¶ 196.

the reports of thirty adverse events and twelve instances of misdosing.[64] And it was aware because *Intercept itself* reported this information to the agency. Plaintiffs' contention that the Individual Defendants were motivated to conceal the very safety issues that their company was reporting to the FDA in order to prevent a negative regulatory response is thus implausible.

Moreover, "the FDA's actions further undermine plaintiffs' *scienter* claim."[65] As explained previously, "'*[s]cienter* can be shown where 'management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public[.]' Yet here, armed with knowledge that Ocaliva patients were misdosed and experienced SAEs, the FDA did not withdraw the drug from the market or otherwise restrict or modify its availability."[66]

Plaintiffs' second allegation requires less of a stretch of the imagination. They contend that the Individual Defendants were motivated to ignore or conceal the adverse event reports in order to prevent a negative response from the market. It is certainly plausible that company executives would improperly shield information from the public to avoid shrinking the company's commercial prospects or hurting its stock price.[67] But, as explained above, the PSLRA requires that

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64 *Id.* ¶¶ 88, 186-190.

65 *Intercept*, 2020 WL 1489831, at *16.

66 *Id.* (quoting *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008)); *see also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 533 (S.D.N.Y. 2015).

67 Plaintiffs in their memorandum argue that defendants were motivated also to ignore safety concerns "in order to avoid a drop in the price of Intercept's stock." DI 96 at 27. Though this precise wording does not appear in the PSAC, the Court disagrees with defendants' assertion that this allegation is "nowhere to be found in the PSAC." DI 99 at 14 n.6. The allegation that defendants were motivated to ignore safety concerns to prevent a negative market reaction immediately follows the allegation that "[s]everal analysts noted during the

fraud be pleaded with particularity, in addition to plausibility.

Plaintiffs simply have not done so. They have alleged only that "the market was closely watching the performance of Ocaliva in PBC patients" because of its potential increased market opportunity, and from this contend that defendants would have been motivated to conceal any safety issues. This generalized concern about market potential is hardly sufficient to demonstrate that defendants acted with "the intent to deceive, manipulate, or defraud."[68]

Plaintiffs' reliance on *Matrixx Initiatives, Inc. v. Siracusano*[69] is misplaced. They argue that the Individual Defendants, like the defendants in *Matrixx*, "elected not to disclose the reports of adverse events not because it believed they were meaningless but because [they] understood [the reports'] likely effect on the market."[70] That case differs in important ways from the facts alleged here.

Matrixx involved a claim that the defendants' statements on the company's revenues and safety of its product, Zicam Cold Remedy, were materially false or misleading in light of the defendants' failure to disclose reports of a possible link between Zicam and anosmia (the loss of

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Class Period that if any safety issues arose during the commercial launch of Ocaliva in PBC patients, approval [for use in other conditions], which was a much larger market opportunity for Intercept, could be in jeopardy." PSAC ¶ 196. In this context, the reference to a "negative market reaction" seemingly refers to the increased market opportunity that would become available to Intercept if Ocaliva was approved to treat other diseases. However, reading the PSAC in the light most favorable to plaintiffs, the allegation could refer also to the general effect on the market, such as a stock price drop.

68 *Hochfelder*, 425 U.S. at 193.

69 563 U.S. 27 (2011).

70 PSAC ¶ 196 (citing *Matrixx*, 563 U.S. at 49).

smell) and lawsuits by Zicam users alleging that Zicam damaged their sense of smell.[71] One research doctor, Dr. Linschoten, had informed the company of studies linking Zicam's main active ingredient to anosmia while another, Dr. Jafek, published an abstract – and had planned to give a presentation – on Zicam induced anosmia, a fact of which the defendants became aware.[72]

Matrixx eventually issued a press release affirmatively denying that Zicam caused anosmia, referring to reports of this adverse event as "completely unfounded and misleading."[73] Critically, however, the company "had evidence of a biological link between Zicam's key ingredient and anosmia, and it had not conducted any studies of its own to disprove that link."[74] In addition, Matrixx had prevented Dr. Jafek from naming Zicam in his presentation, was "sufficiently concerned" about the information it had received from Dr. Linschoten that it informed her that it had hired a had consultant to review the product, and in response to Dr. Jafek's presentation, Matrixx convened a panel of scientists and physicians to review whether Zicam caused anosmia.[75] Taken together, the company's actions demonstrated that it believed the reports indicated something "meaningful" about the adverse reactions to Zicam, and its steps to conceal negative information from the market "g[a]ve rise to a 'cogent and compelling inference'" of *scienter*.[76] Nothing of the

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71 *Matrixx*, 563 U.S. at 30-33.

72 *Id.* at 32-33.

73 *Id.* at 35.

74 *Id.* at 47.

75 *Id.* at 32-33, 49.

76 *Id.* at 49.

sort is alleged here.

For the reasons set forth above, plaintiffs have not alleged facts sufficient to show that an inference of *scienter* is at least – or more – compelling than the non-actionable inference of the Individual Defendant's negligence in failing to review certain data prior to speaking.

2. Corporate Scienter

Corporate *scienter* is alleged by pleading facts sufficient to create a strong inference either (1) "that someone whose intent could be imputed to the corporation acted with the requisite *scienter*," or (2) that the statements "would have been approved by corporate officials sufficiently knowledgeable about the company to know that those statements were misleading."[77] The most "straightforward" way to do so is to plead facts sufficient to show *scienter* for the individual defendant who made the alleged misstatement.[78] Where other officers or directors were involved in the dissemination of the fraud, there must be some "connective tissue between those employees and the alleged misstatements."[79] It is thus insufficient to "separately allege misstatements by some individuals and knowledge belonging to some others where there is no strong inference that, in fact, there was a connection between the two."[80]

Plaintiffs argue that the PSAC pleads corporate *scienter* through the allegations that

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77 *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 177 (2d Cir. 2015) (internal quotation marks and citation omitted).

78 *Dynex*, 531 F.3d at 195.

79 *Jackson v. Abernathy*, 960 F.3d 94, 99 (2d Cir. 2020).

80 *Id.* (Internal quotation marks and citation omitted).

management-level employees had access to information regarding the SAEs, potential side effects ("PSEs") and misdosing, and at times spoke on the company's behalf. For example, the PSAC alleges that Intercept's chief medical officer was responsible for supervising the clinical development of Ocaliva, tasked with monitoring safety issues, overseeing data on the SAEs, PSEs, and dosing, and presenting safety data on Intercept's behalf.[81] The PSAC alleges also that various management-level (and non-management level) employees in Intercept's pharmacovigilance and market access departments had access to information about the prescribed doses and the safety and tolerance of Ocaliva, and that the executive director of the medical safety and pharmacovigilance department was responsible for speaking on Intercept's behalf.[82]

These new allegations bring plaintiffs closer to alleging *scienter* sufficiently. The critical pieces, however, are missing. There are no allegations connecting the relevant employees to the alleged misstatements. It is not enough to allege that certain employees with access to certain information were generally responsible for speaking on behalf of the company.[83] Instead, there must be allegations sufficient to show that those management-level employees knew both of the reports of adverse events and misdosing "and approved or were aware of the allegedly misleading

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81 PSAC ¶ 187.

82 *Id.* ¶¶ 188-91.

83 In its prior opinion, the Court explained that "while there is no seniority prerequisite for employee *scienter* to be imputed to the corporation, it is generally sufficient where the employee enjoy[s] some oversight over the company's public-facing representations." *Intercept*, 2020 WL 1489831, at *17 (internal quotation marks and citations omitted). Plaintiffs' allegations were thus deficient in part because the amended complaint was "silent as to any particular department positions or hierarchy." *Id.* However, this was only one of several deficiencies. Critically, the amended complaint did not "bridge the gap" between the alleged misstatements and Intercept employees' knowledge of their falsity. *Id.*

statements."[84] Without such allegations, the Court "can therefore only guess what role those employees played in crafting or reviewing the challenged statements and whether it would be otherwise fair to charge the Corporate Defendants with their knowledge."[85] Accordingly, plaintiffs have failed to set forth allegations sufficient to allege corporate *scienter*.

3. Additional Allegations of Scienter: EMA Documents and Litigation

In May 2018, the European Medical Agency ("EMA") granted plaintiffs' application for access to Intercept's Periodic Safety Update Report ("PSURs") for the period of December 12, 2016 through June 11, 2017, the EMA's pharmacovigilance risk assessment committee assessment report, and Intercept's approved risk management plan as of March 2018.[86] PSURs provide an evaluation of the "risk-benefit balance of [a] product, taking into account new or emerging safety information in the context of cumulative information on risk and benefits."[87] Intercept was required to submit PSURs as part of Ocaliva's approval in the European Union.[88]

In June 2018, Intercept filed a lawsuit challenging the EMA's decision.[89] During the hearing on this issue before the European General Court ("EGC"), Intercept allegedly

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84 *Id.*

85 *Jackson*, 960 F.3d at 99.

86 PSAC ¶ 198.

87 *Id.* ¶ 197.

88 *Id.*

89 *Id.* ¶¶ 199-200.

mischaracterized the nature of the PSLRA's automatic discovery stay.[90] The EGC dismissed the lawsuit and Intercept's appeal is pending.[91] As a result, plaintiffs have not received the PSURs.[92]

Plaintiffs argue that defendants' "improper gamesmanship" to prevent the disclosure of the PSURs "confirms" that those documents contain relevant information concerning the SAEs and PSEs.[93] They contend also that the PSURs establishes *scienter* for the Company because those reports "necessarily included" an analysis of the SAEs and potential side effects caused by Ocaliva.

In is prior opinion, the Court rejected the argument that plaintiffs demonstrated *scienter* through its allegations concerning Intercept's challenge to the EMA's decision.[94] This was so because "the complaint merely detail[ed] the chronology" and did not contain any facts sufficient to show "how Intercept's lawful action raise[d] an inference of *scienter*."[95]

Although plaintiffs have added to their allegations, once again, plaintiffs have only "detail[ed] the chronology" of Intercept's challenge of the EMA's decision and have not raised a strong inference of *scienter*. Even if true, plaintiffs' position that the European lawsuit was "frivolous" and an attempt to shield plaintiffs from certain documents are insufficient conclusory

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90 *Id.* ¶ 201. Plaintiffs sought leave to submit this evidence in further support of the motion to partially lift the PSLRA discovery stay. The Court denied both motions. DI 87, 88.

91 PSAC ¶¶ 202-03.

92 *Id.* ¶ 203.

93 DI 96 at 29-30.

94 *Intercept*, 2020 WL 1489831, at *19.

95 *Id.*

allegations. As is their allegation that PSURs "will show" that Intercept had knowledge of or access to Ocaliva's safety data. For the reasons explained above, mere access to this information by someone at Intercept does not demonstrate *scienter*. Accordingly, plaintiffs allegations concerning the EMA litigation fail once more.

Conclusion

For the foregoing reasons, plaintiffs' motion [DI 95] is denied.

SO ORDERED.

Dated: September 9, 2020

Lewis A. Kaplan
United States District Judge